

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024
or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from _____ to _____

Commission File Number: 001-36866

Summit Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

37-1979717

(I.R.S. Employer Identification No.)

**601 Brickell Key Drive, Suite 1000,
Miami, FL**

(Address of principal executive offices)

33131

(Zip Code)

305-203-2034

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	SMMT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 23, 2024, there were 737,448,146 shares of common stock, par value \$0.01 per share, outstanding.

PART I

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, regarding the future financial performance, business prospects and growth of Summit Therapeutics Inc., that involve substantial risks and uncertainties. All statements contained in this Quarterly Report on Form 10-Q, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the ability to develop a successful product candidate under the License Agreement (as defined below);
- our ability to raise sufficient additional funds to make payments under the License Agreement, and fund ongoing operations and capital needs;
- the timing of and the ability to effectively execute clinical development of ivonescimab;
- the timing, costs, conduct and outcomes of clinical trials for any product candidates;
- our plans with respect to possible future collaborations and partnering arrangements;
- the potential benefits of possible future acquisitions or investments in other businesses, products or technologies;
- our plans to pursue research and development of other future product candidates;
- our estimates regarding the potential market opportunity and patient population for commercializing our product candidates, if approved for commercial use;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements with third parties, such as contract research organizations, contract manufacturing organizations, suppliers, and distributors;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations in the United States and in foreign countries;
- the timing and likelihood of regulatory filings and approvals for our product candidates;
- whether regulatory authorities determine that additional trials or data are necessary in order to accept a new drug application for review and/or approval;
- our competitive position;
- our use of our existing cash, cash equivalents and marketable securities;
- our ability to attract and retain key scientific or management personnel;
- the impact of public health epidemics, the response to such epidemics and the potential effects of such epidemics on our clinical trials, business, financial results, supply chain and market; and
- other risks and uncertainties, including those described under the heading “Risk Factors” included in our most recent Annual Report on Form 10-K for the year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission (“SEC”) on February 20, 2024.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Report, particularly in the “Risk Factors” section in this Report, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Report and the documents that we have filed as exhibits to this Report completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

Summit Therapeutics Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 93,775	\$ 71,425
Restricted cash	323	—
Short-term investments	393,122	114,817
Prepaid expenses and other current assets	2,410	2,622
Research and development tax credit receivable	660	848
Total current assets	490,290	189,712
Non-current assets:		
Property and equipment, net	265	204
Right-of-use assets	7,976	5,859
Goodwill	1,991	1,893
Research and development tax credit receivable	467	959
Other assets	1,863	4,322
Total assets	\$ 502,852	\$ 202,949
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,252	\$ 2,667
Accrued liabilities	18,477	8,783
Accrued compensation	7,961	5,429
Lease liabilities	3,792	2,809
Other current liabilities	1,027	717
Promissory note payable to a related party	24,500	—
Total current liabilities	59,009	20,405
Non-current liabilities:		
Lease liabilities, net of current portion	4,207	3,290
Other non-current liabilities	1,716	1,562
Promissory note payable to a related party	—	100,000
Total liabilities	64,932	125,257
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 20,000,000 shares authorized; none issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.01 par value: 1,000,000,000 shares authorized; 737,094,965 and 701,660,053 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	7,371	7,017
Additional paid-in capital	1,586,227	1,066,381
Accumulated other comprehensive loss	(2,308)	(2,448)
Accumulated deficit	(1,153,370)	(993,258)
Total stockholders' equity	437,920	77,692
Total liabilities and stockholders' equity	\$ 502,852	\$ 202,949

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Summit Therapeutics Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	37,724	\$ 15,323	99,395	34,657
Acquired in-process research and development	—	—	15,007	520,915
General and administrative	20,390	5,434	46,090	18,690
Total operating expenses	58,114	20,757	160,492	574,262
Other operating (expense) income, net	(264)	265	108	822
Operating loss	(58,378)	(20,492)	(160,384)	(573,440)
Other income (expense), net	2,124	(776)	272	(4,921)
Net loss	<u>\$ (56,254)</u>	<u>\$ (21,268)</u>	<u>\$ (160,112)</u>	<u>\$ (578,361)</u>
Net loss per share:				
Basic and diluted	\$ (0.08)	\$ (0.03)	\$ (0.22)	\$ (0.98)
Weighted-average shares used to compute net loss per share:				
Basic and diluted	726,656,045	697,739,477	712,168,381	592,366,880
Comprehensive loss:				
Net loss	\$ (56,254)	\$ (21,268)	\$ (160,112)	\$ (578,361)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(155)	108	(175)	(20)
Reclassification of cumulative currency translation gain to other expense, net	—	—	—	(419)
Reclassification of unrealized loss on short-term investments to other expense, net	—	—	3	—
Net unrealized gains on short-term investments	346	6	312	9
Comprehensive loss	<u>\$ (56,063)</u>	<u>\$ (21,154)</u>	<u>\$ (159,972)</u>	<u>\$ (578,791)</u>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Summit Therapeutics Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)
(Unaudited)

Three Months Ended September 30, 2024

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2024	724,320,201	\$ 7,243	\$ 1,287,447	\$ (2,499)	\$ (1,097,116)	\$ 195,075
Private placement of common stock, net of offering costs of \$140	10,352,418	104	234,756	—	—	234,860
Issuance of common stock under stock purchase plans and exercise of stock options and warrants	615,253	6	1,638	—	—	1,644
Proceeds from at-the-market offering, net of commissions and offering costs of \$1,190	1,807,093	18	43,015	—	—	43,033
Stock-based compensation	—	—	19,371	—	—	19,371
Net other comprehensive loss	—	—	—	191	—	191
Net loss	—	—	—	—	(56,254)	(56,254)
Balance at September 30, 2024	<u>737,094,965</u>	<u>\$ 7,371</u>	<u>\$ 1,586,227</u>	<u>\$ (2,308)</u>	<u>\$ (1,153,370)</u>	<u>\$ 437,920</u>

Nine Months Ended September 30, 2024

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	701,660,053	\$ 7,017	\$ 1,066,381	\$ (2,448)	\$ (993,258)	\$ 77,692
Private placements of common stock, net of offering costs of \$140	32,574,640	326	434,534	—	—	434,860
Issuance of common stock under stock purchase plans and exercise of stock options and warrants	1,053,179	10	2,331	—	—	2,341
Proceeds from at-the-market offering, net of commissions and offering costs of \$1,190	1,807,093	18	43,015	—	—	43,033
Stock-based compensation	—	—	39,966	—	—	39,966
Net other comprehensive loss	—	—	—	140	—	140
Net loss	—	—	—	—	(160,112)	(160,112)
Balance at September 30, 2024	<u>737,094,965</u>	<u>\$ 7,371</u>	<u>\$ 1,586,227</u>	<u>\$ (2,308)</u>	<u>\$ (1,153,370)</u>	<u>\$ 437,920</u>

Three Months Ended September 30, 2023

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2023	697,685,365	\$ 6,976	\$ 1,050,483	\$ (2,437)	\$ (935,423)	\$ 119,599
Issuance of common stock under stock purchase plans and exercise of stock options and warrants	165,943	2	227	—	—	229
Stock-based compensation	—	—	705	—	—	705
Net other comprehensive income	—	—	—	114	—	114
Net loss	—	—	—	—	(21,268)	(21,268)
Balance at September 30, 2023	<u>697,851,308</u>	<u>\$ 6,978</u>	<u>\$ 1,051,415</u>	<u>\$ (2,323)</u>	<u>\$ (956,691)</u>	<u>\$ 99,379</u>

Nine Months Ended September 30, 2023

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	211,091,425	\$ 2,110	\$ 504,767	\$ (1,893)	\$ (378,330)	\$ 126,654
Rights offering of common stock, net of offering costs of \$619	476,190,471	4,762	494,619	—	—	499,381
Issuance of common stock under stock purchase plans and exercise of stock options and warrants	569,412	6	874	—	—	880
Issuance of common stock in lieu of cash for Akeso upfront payment	10,000,000	100	45,800	—	—	45,900
Stock-based compensation	—	—	5,355	—	—	5,355
Net other comprehensive loss	—	—	—	(430)	—	(430)
Net loss	—	—	—	—	(578,361)	(578,361)
Balance at September 30, 2023	<u>697,851,308</u>	<u>\$ 6,978</u>	<u>\$ 1,051,415</u>	<u>\$ (2,323)</u>	<u>\$ (956,691)</u>	<u>\$ 99,379</u>

Certain prior period amounts have been reclassified to conform to current fiscal year presentation

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

Summit Therapeutics Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (160,112)	\$ (578,361)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense	—	5,852
Amortization of discount on short-term investments	(4,926)	(1,716)
Unrealized foreign exchange loss (gain)	400	(370)
Reclassification of currency translation gain	—	(419)
Impairment of fixed assets	—	474
Depreciation	67	168
Gain on disposal of assets	—	(111)
Stock-based compensation	39,966	5,355
Acquired in-process research and development expense	15,007	520,915
Change in operating assets and liabilities:		
Accounts receivable	—	359
Prepaid expenses	572	(3,554)
Other current and long-term assets	2,105	(3,378)
Research and development tax credit receivable	738	4,346
Accounts payable	486	2,935
Accrued liabilities	9,894	(7,728)
Other long-term liabilities	70	58
Accrued compensation	2,515	(2,145)
Operating lease right-of-use assets and lease liabilities, net	(215)	19
Net cash used in operating activities	(93,433)	(57,301)
Cash flows from investing activities:		
Purchases of property and equipment	(125)	(126)
Proceeds from sale of property and equipment	—	226
Purchase of short-term investments	(530,544)	(321,023)
Maturities and sales of short-term investments	256,853	147,596
Payments to Akeso for upfront milestone payments and associated direct transaction costs	(15,007)	(475,015)
Net cash used in investing activities	(288,823)	(648,342)
Cash flows from financing activities:		
Proceeds from the issuance of common stock via private placements, net of offering costs	434,961	—
Proceeds from the issuance of common stock under at-the-market offering, net of commissions and offering costs	43,037	—
Proceeds from the issuance of common stock for rights offering, net of offering costs	—	104,067
Repayment of related party promissory notes	(75,500)	(24,686)
Proceeds received related to the exercise of warrants	101	—
Proceeds received related to employee stock awards and purchase plans	2,240	880
Net cash provided by financing activities	404,839	80,261
Effect of exchange rate changes on cash	90	567
Increase (decrease) in cash and cash equivalents	22,673	(624,815)
Cash, cash equivalents and restricted cash at beginning of period	71,425	648,607
Cash, cash equivalents and restricted cash at end of period	\$ 94,098	\$ 23,792
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest on related party promissory notes	\$ 1,501	\$ 7,711
Cash paid for income taxes	\$ —	\$ 52
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Consideration for the issuance of common stock for rights offering used to satisfy a portion of a related party promissory note (Note 14)	\$ —	\$ 395,314
Offering costs included in accounts payable and accrued expenses	\$ 105	\$ —
Issuance of common stock pursuant to the Akeso License Agreement (Note 7)	\$ —	\$ 45,900
Lease assets obtained in exchange for operating lease liabilities	\$ 4,216	\$ 4,245

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

1. Nature of Business and Operations

Summit Therapeutics Inc. (“we”, “Summit” or the “Company”) is a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs.

The Company’s current lead development candidate is ivonescimab, a novel, potential first-in-class bispecific antibody intending to combine the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF compound into a single molecule. On December 5, 2022, the Company entered into a Collaboration and License Agreement (the “License Agreement”) with Akeso, Inc. and its affiliates (“Akeso”) pursuant to which the Company has in-licensed ivonescimab as further described in Note 7. Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, Japan, and through the subsequent amendment with Akeso signed on June 3, 2024, expanded the Company’s licensed territories to include the Latin America, Middle East and Africa regions (collectively, and as expanded, the “Licensed Territory”). The License Agreement and transaction closed in January 2023 following customary waiting periods. The Company’s operations are focused on the development of ivonescimab and other future activities, as the Company determines.

The Company has begun its development for ivonescimab in non-small cell lung cancer (“NSCLC”), specifically launching Phase III clinical trials in the following proposed indications:

- a) ivonescimab combined with chemotherapy in patients with epidermal growth factor receptor (“EGFR”)-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with a third-generation EGFR tyrosine kinase inhibitor (“TKI”) (“HARMONi”); and
- b) ivonescimab combined with chemotherapy in first-line metastatic squamous NSCLC patients (“HARMONi-3”)

In addition, the Company intends to initiate a Phase III clinical study in the following proposed indication in early 2025:

- c) ivonescimab monotherapy in first-line metastatic NSCLC patients with high PD-L1 expression (“HARMONi-7”).
 - The sample size for this study is currently planned to have an estimated 780 patients with two primary endpoints, progression-free survival (PFS) and overall survival (OS)

In October 2024, the Company completed enrollment in its HARMONi clinical trial. The Company expects to disclose topline results from HARMONi in mid-2025, depending upon maturation of the data per the protocol.

The Company also intends to amend the protocol for its HARMONi-3 study to include both squamous and non-squamous patients without actionable genomic alterations, adjust the primary endpoint for HARMONi-3 to include PFS in addition to OS, and adjust the sample size to include an estimated 1,080 patients.

The entry into the License Agreement with Akeso represented a significant change in the Company’s strategy and its future operations are focused on the development of ivonescimab and other future activities as the Company determines. The Company’s portfolio also includes ridinilazole, a product candidate for treating patients suffering from *Clostridioides difficile* infection, also known as *C. difficile* infection, or CDI, and SMT-738, the first of a novel class of precision antibiotics for combating multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae (“CRE”) infections. All prior development activities related to ridinilazole and SMT-738 have been terminated; the Company may explore partnership opportunities for both assets.

2. Basis of Presentation and Use of Estimates

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) and pursuant to the rules and regulations of the SEC. Accordingly, certain information and disclosures required by U.S. GAAP for complete consolidated financial statements are not included herein. All intercompany accounts and transactions have been eliminated in consolidation. The interim financial data as of September 30, 2024 and for the three and nine months ended September 30, 2024 are unaudited; however, in the

Summit Therapeutics Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(in thousands, except share and per share data)

opinion of management, the interim data includes all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of the results for the interim periods. The condensed consolidated balance sheet presented as of December 31, 2023 has been derived from the consolidated audited financial statements as of that date. The results of the period are not necessarily indicative of full year results or any other interim period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto of the Company which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on February 20, 2024. The financial results of the Company's activities are reported in United States Dollars.

Certain reclassifications have been made to the prior years' financial statements to conform to current year presentation.

Use of Estimates

The preparation of these unaudited condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to accrued research and development expenses, stock-based compensation, goodwill, other long-lived assets and income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

3. Summary of Significant Accounting Policies and Recently Issued or Adopted Accounting Pronouncements

Summary of Accounting Policies

The significant accounting policies used in the preparation of these condensed consolidated financial statements for the nine months ended September 30, 2024 are consistent with those discussed in Note 4 to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, except as updated below:

Marketable Securities

Marketable securities consist of investments with original maturities greater than ninety days from the date of acquisition. The Company classifies investments with maturities of greater than 90 days as short-term, based on the liquid nature of the securities and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of investments as available-for-sale. Accordingly, these investments are recorded at fair value, which is based on quoted market prices or other observable inputs. Unrealized gains and losses are recorded as a component of other comprehensive income (loss). Realized gains and losses are determined on a specific identification basis and are included in other (expense) income. Amortization and accretion of discounts and premiums are also recorded in other (expense) income.

When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. This estimate is limited to the amount by which fair value is less than amortized cost. The credit-related impairment amount is recognized in the condensed consolidated statements of operations and comprehensive loss and the remaining impairment amount and unrealized gains are reported as a component of accumulated other comprehensive income (loss) in shareholders' equity. Credit losses are recognized through the use of an allowance for credit losses account and subsequent improvements in expected credit losses are recognized as a reversal of the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis the allowance for credit loss is written off and the excess of the amortized cost basis of the asset over its fair value is recorded in the condensed consolidated statements of operations and comprehensive loss.

Recently Issued or Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU 2023-07"), Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, to provide more disaggregated expense information about a public entity's reportable segments. The amendments in this update should be applied retrospectively and are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company is currently assessing the impact of the adoption of this guidance on its financial statements and disclosures.

Summit Therapeutics Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
(in thousands, except share and per share data)

4. Liquidity and Capital Resources

During the three and nine months ended September 30, 2024, the Company incurred a net loss of \$56,254 and \$160,112, respectively, and cash flows used in operating activities for the nine months ended September 30, 2024 was \$93,433. As of September 30, 2024, the Company had an accumulated deficit of \$1,153,370, cash and cash equivalents of \$93,775, and short-term investments in U.S. treasury securities of \$393,122. The Company expects to continue to generate operating losses for the foreseeable future.

The Company recently raised gross proceeds of \$235,000 related to a recent private placement and \$44,223 related to the Company's at-the-market sales agreement ("ATM Agreement"), both described further in Note 15. With these recent financings, the Company has evaluated and concluded its cash, cash equivalents, and short-term investments, provide sufficient cash to fund its operating cash needs for at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

Until the Company can generate substantial revenue and achieve profitability, the Company will need to raise additional capital to fund its ongoing operations and capital needs. The Company continues to evaluate options to further finance its operating cash needs for its product candidates through a combination of some, or all, of the following: equity and debt offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations, and marketing, distribution or licensing arrangements. There is no assurance, however, that additional financing will be available when needed or that management of the Company will be able to obtain financing on terms acceptable to the Company. If the Company is unable to obtain funding when required in the future, the Company could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects.

5. Segment Reporting

The Company's chief operating decision makers (the "CODM function"), which are the Company's CEOs, Mr. Duggan and Dr. Zanganeh, utilize consolidated financial information to make decisions about allocating resources and assessing performance for the entire Company. The CODM function approves of key operating and strategic decisions, including key decisions in clinical development and clinical operating activities, entering into significant contracts, such as revenue contracts and collaboration agreements and approves the Company's consolidated operating budget. The CODM function views the Company's operations and manages its business as a single reportable operating segment. The Company's single operating segment covers the Company's research and development activities, primarily comprising of oncology product research activities (including ivonescimab). As the Company operates as one operating segment, all required financial segment information can be found in these condensed consolidated financial statements.

The Company operates in two geographic regions: the U.K. and the U.S. The following table summarizes the Company's long-lived assets, which include the Company's property and equipment, net and right-of-use assets by geography:

	September 30, 2024	December 31, 2023
United Kingdom	\$ 660	\$ 808
United States	7,581	5,254
Total	<u>\$ 8,241</u>	<u>\$ 6,062</u>

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6. Other Operating (Expense) Income, net

The following table sets forth the components of other operating (expense) income, net by category:

Other operating (expense) income, net by category:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development tax credits	\$ (264)	\$ 265	\$ 108	\$ 768
Grant income from CARB-X (as defined below)	—	—	—	45
Other income	—	—	—	9
Total other operating (expense) income, net	<u>\$ (264)</u>	<u>\$ 265</u>	<u>\$ 108</u>	<u>\$ 822</u>

Research and development tax credits

Income from tax credits consist of research and development ("R&D") tax credits received in the U.K. The Company benefits from the Small and Medium Enterprise Program ("SME Program") U.K. research and development tax credit cash rebate regime, and The Research and Development Expenditure Credit ("The RDEC scheme"), a UK government tax incentive that promotes innovation amongst UK's larger businesses. Qualifying expenditures largely comprise of employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which the Company does not receive income. Tax credits related to the SME Program and The RDEC scheme are recorded as other operating income in the consolidated statements of operations and other comprehensive loss. Under these schemes, the Company receives cash payments that are not dependent on the Company's pre-tax net income levels.

Based on criteria established by His Majesty's Revenue and Customs ("HMRC"), a portion of expenditures being carried out in relation to the Company's pipeline research and development, clinical trials management and third-party manufacturing development activities are eligible for the SME regime and the Company expects such elements of research and development expenditure incurred in its UK entities will also continue to be eligible for the SME regime for future periods.

R&D Tax credits decreased for the three and nine months ended September 30, 2024 as management updated its estimates for qualifying expenditures. As of September 30, 2024, the current and non-current research and development tax credit receivable was \$660 and \$467, respectively. As of December 31, 2023, the current and non-current research and development tax credit receivable was \$848 and \$959, respectively.

CARB-X (as defined below)

In May 2021, the Company announced the selection of a new preclinical candidate, SMT-738, from the DDS-04 series for development in the fight against multi-drug resistant infections, specifically Carbapenem-resistant Enterobacteriaceae ("CRE") infections. Simultaneously, the Company announced it had received an award from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator program ("CARB-X") to progress this candidate through preclinical development and Phase Ia clinical trials. The award committed initial funding of up to \$4,100, with the possibility of up to another \$3,700 based on the achievement of future milestones. As of September 30, 2024, based on translation of historical foreign currency amounts in the period, the Company has recognized \$2,920 of cumulative income since contract inception.

7. Akeso Collaboration and License Agreement

On December 5, 2022, the Company entered into a Collaboration and License Agreement (the "License Agreement") with Akeso, Inc. and its affiliates ("Akeso") pursuant to which the Company is in-licensing Akeso's breakthrough bispecific antibody, ivonescimab. The License Agreement and transaction closed in January 2023 following customary waiting periods.

Ivonescimab, known as AK112 in China and Australia, and also as SMT112 in the United States, Canada, Europe, and Japan, is a novel, potential first-in-class bispecific antibody intending to combine the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF into a single molecule. Ivonescimab was engineered to bring two well established oncology targeted mechanisms together. Ivonescimab is currently in clinical development and, pursuant to

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the terms of the License Agreement, Summit will design and conduct the clinical trial activities to support regulatory filings in the Licensed Territory that Summit will submit.

Pursuant to the terms of the License Agreement, Summit will have final decision-making authority with respect to clinical development strategy and execution in the Licensed Territory. For co-joined studies in which both Summit and Akeso participate, mutual agreement is required for material decisions; Summit retains the exclusive decision making with respect to participating in, and continuing its participation in, co-joined studies. Pursuant to the terms of the License Agreement, Summit will have final decision-making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters in the Licensed Territory. In connection with the License Agreement, the Company has also entered into a Supply Agreement with Akeso, pursuant to which Summit agrees to purchase a certain portion of drug substance for clinical and commercial supply. Summit is not assuming any liabilities (including contingent liabilities), acquiring any physical assets or trade names, or hiring or acquiring any employees from Akeso in connection with the License Agreement. Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan.

In exchange for the rights obtained, the Company made an upfront payment of \$500,000 to Akeso, of which \$274,900 was paid in cash and, pursuant to the License Agreement and Issuance Agreement, Akeso elected to receive 10,000,000 shares of the Company's common stock in lieu of \$25,100 cash. The remaining \$200,000 amount of the upfront payment was paid on March 6, 2023.

Effective June 3, 2024, the Company and Akeso entered into an amendment (the "Second Amendment") to the License Agreement to expand the Company's territories covered under the License Agreement to include the Latin America, Middle East and Africa regions. Pursuant to the Second Amendment, the Company paid an upfront payment to Akeso of \$15,000 in the third quarter of 2024. Akeso will also be eligible to receive up to an additional \$55,000 upon the achievement of certain commercial milestones. Except as specifically modified by the Second Amendment, the terms and conditions of the License Agreement remain in full force and effect.

The Company has accounted for the License Agreement and Second Amendment to acquire the rights to develop and commercialize ivonescimab as the acquisition of an asset. All of the consideration relates to ivonescimab and technological feasibility of the asset has not yet been established since ivonescimab is in clinical development. As such, the Company has expensed the consideration as acquired in-process research and development upon closing of the transaction in the condensed consolidated statement of operations and comprehensive loss. Acquired in-process research and development expense for the three and nine months ended September 30, 2024 was nil and \$15,007, respectively, the \$15,007 being the upfront payment of \$15,000 and immaterial transaction costs for the Second Amendment. Acquired in-process research and development expense for the three and nine months ended September 30, 2023 was nil and \$520,915, respectively, for which the \$520,915 is comprised of the \$474,900 paid in cash, the fair value of the 10,000,000 shares of common stock on the date of closing the transaction of \$45,900, and \$115 of direct transactions costs incurred for the License Agreement.

In addition to the payments already made to Akeso, under the License Agreement and Second Amendment, there are additional potential milestone payments of up to \$4,555,000, as Akeso will be eligible to receive regulatory milestones of up to \$1,050,000 and commercial milestones of up to \$3,505,000. In addition, Akeso will be eligible to receive low double-digit royalties on net sales.

8. Other Income (Expense), net

The following table sets forth the components of other income (expense), net:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Foreign currency gains/(losses)	\$ 242	\$ (475)	\$ 206	\$ 344
Interest expense on promissory notes payable to related parties	(2,455)	(2,722)	(8,677)	(13,564)
Investment income ⁽¹⁾	4,337	2,485	8,744	8,028
Reclassification of cumulative currency translation gain ⁽²⁾	—	—	—	419
Other expense, net	—	(64)	—	(148)
Total other income (expense), net	\$ 2,124	\$ (776)	\$ 272	\$ (4,921)

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(1) Immaterial realized losses have been reclassified from accumulated other comprehensive loss to other income (expense), net for the nine months ended September 30, 2024. No such reclasses occurred in the prior year periods presented.

(2) During the nine months ended September 30, 2023, the Company dissolved certain dormant entities and as a result, \$419 of cumulative foreign currency translation adjustments were re-classified from accumulated other comprehensive loss relating to these entities.

9. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	\$ (56,254)	\$ (21,268)	\$ (160,112)	\$ (578,361)
Basic weighted average number of shares of common stock outstanding	726,656,045	697,739,477	712,168,381	592,366,880
Diluted weighted average number of shares of common stock outstanding	726,656,045	697,739,477	712,168,381	592,366,880
Basic net loss per share	\$ (0.08)	\$ (0.03)	\$ (0.22)	\$ (0.98)
Diluted net loss per share	\$ (0.08)	\$ (0.03)	\$ (0.22)	\$ (0.98)

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the diluted net loss by the weighted-average number of common shares outstanding for the period, including potentially dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods, as the inclusion of all potential common share equivalents outstanding would have been anti-dilutive.

The following potentially dilutive securities were excluded from the computation of the diluted net loss per share of common stock for the periods presented because their effect would have been anti-dilutive:

	September 30,	
	2024	2023
Options to purchase common stock	68,579,042	20,548,267
Warrants	4,945,669	5,821,137
Shares expected to be purchased under employee stock purchase plan	86,550	247,357
Total	<u>73,611,261</u>	<u>26,616,761</u>

Stock options that are outstanding and contain performance-based or market-based vesting criteria for which the performance or market conditions have not been met are excluded from the presentation of common stock equivalents outstanding in the table above.

10. Fair Value Measurements and Short-Term Investments

In accordance with the provisions of fair value accounting, a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability and defines fair value based on the exit price model.

The fair value measurement guidance establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The guidance describes three levels of inputs that may be used to measure fair value:

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Level 1

Quoted prices in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2

Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Level 2 assets and liabilities include debt securities with quoted prices that are traded less frequently than exchange-traded instruments or securities or derivative contracts that are valued using a pricing model with inputs that are observable in the market or can be derived principally from or corroborated by observable market data.

Level 3

Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the Company categorizes such assets and liabilities based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset.

The following tables set forth the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2024 and December 31, 2023:

	Fair Value Measurements as of September 30, 2024 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 50,937	\$ —	\$ —	\$ 50,937
U.S. Government treasury bills	—	30,519	—	30,519
Short-term investments:				
U.S. Government treasury bills	—	393,122	—	393,122
Total financial assets	\$ 50,937	\$ 423,641	\$ —	\$ 474,578

	Fair Value Measurements as of December 31, 2023 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 21,016	\$ —	\$ —	\$ 21,016
U.S. Government treasury bills	—	39,341	—	39,341
Short-term investments:				
U.S. Government treasury bills	—	114,817	—	114,817
Total financial assets	\$ 21,016	\$ 154,158	\$ —	\$ 175,174

The tables above do not include cash at September 30, 2024 and December 31, 2023 of \$12,318 and \$11,068, respectively.

The Company believes that the carrying amounts of prepaid expenses, other current assets, accounts payable, and accrued expenses approximates their fair values due to the short-term nature of those instruments. The carrying value of the Company's promissory note approximates its fair value and the current interest rate of the note outstanding when compared to market interest rates (which represents a Level 2 measurement). Refer to Note 14 for further details.

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The following table sets forth the Company's short-term investments as of September 30, 2024 and December 31, 2023, which have a contractual maturity of less than one year:

September 30, 2024					
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Credit (Loss)	Fair Value
Assets					
U.S. Government treasury bills	\$ 392,774	\$ 348	\$ —	\$ —	\$ 393,122
Total	\$ 392,774	\$ 348	\$ —	\$ —	\$ 393,122
December 31, 2023					
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Credit (Loss)	Fair Value
Assets					
U.S. Government treasury bills	\$ 114,781	\$ 36	\$ —	\$ —	\$ 114,817
Total	\$ 114,781	\$ 36	\$ —	\$ —	\$ 114,817

Realized gains and losses for the three and nine months ended September 30, 2024 and September 30, 2023 were immaterial and nil, respectively.

11. Goodwill

As of September 30, 2024 and December 31, 2023, goodwill was \$1,991 and \$1,893, respectively. Changes in the gross carrying amount of goodwill at September 30, 2024 as compared to December 31, 2023, are the result of changes in foreign currency. As of December 31, 2023, the Company performed its annual impairment assessment of goodwill and determined that it is more likely than not that the fair value of the reporting unit exceeds its carrying amount. There have been no goodwill impairments recognized during the three and nine months ended September 30, 2024.

12. Leases

The Company has operating leases for real estate. The Company does not have any finance leases.

In the first fiscal quarter of 2024, the Company recorded \$4,216 of additional right-of-use assets related to a new lease for office space that commenced during the period for its Miami, Florida headquarters location ("Miami HQ"). Total future lease payments as of September 30, 2024, which include base rent and sales tax, are approximately \$4,342 on an undiscounted basis. This lease commenced on February 1, 2024 and has a term of 64 months. As of September 30, 2024 the Company has \$323 of restricted cash associated with an irrevocable letter of credit required by the landlord to enter into this lease. The carrying value of the right-of-use assets as of September 30, 2024 and December 31, 2023 was \$7,976 and \$5,859, respectively.

13. Research and Development Prepaid Expenses and Accrued Liabilities

Included within prepaid expenses and other current assets at September 30, 2024 and December 31, 2023 is \$746 and \$1,466, respectively, of prepayments relating to research and development expenditures. Included within accrued liabilities at September 30, 2024 and December 31, 2023 is \$9,578 and \$7,289, respectively, relating to research and development expenditures.

These amounts are determined based on the estimated costs to complete each study or activity related to the ongoing clinical trials for ivonescimab, the estimation of the current stage of completion and the invoices received, as well as predetermined milestones which are not reflective of the current stage of development for prepaid expenses. However, prepaid expenses decrease and accrued liabilities increase as the activities progress, and if actual costs incurred exceed the prepaid expenses, an accrual will be recorded for the liability. The key sensitivity is the estimated current stage of completion of each study or activity, which is based on information received from the supplier and the Company's operational knowledge of the work completed under those contracts.

14. Promissory Note Payable to Related Parties

Current promissory note payable to a related party was \$24,500 as of September 30, 2024 and non-current promissory note payable to a related party as of December 31, 2023 was \$100,000.

December 2022 Promissory Note

On December 6, 2022, the Company entered into a Note Purchase Agreement (the "Note Purchase Agreement"), with Mr. Duggan and Dr. Zanganeh, pursuant to which the Company agreed to sell to each of Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the aggregate amount of \$520,000. Pursuant to the Note Purchase Agreement, the Company issued to Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the amount of \$400,000 (the "Duggan February Note") and \$20,000 (the "Zanganeh Note"), respectively, which would mature and become due on February 15, 2023 and an unsecured promissory note to Mr. Duggan in the amount of \$100,000 (the "Duggan September Note" and together with the Duggan February Note and the Zanganeh Note, the "December 2022 Notes"), which was originally due on September 15, 2023. The maturity dates of the December 2022 Notes could be extended one or more times at the Company's election, but in no event to a date later than September 6, 2024. In addition, if the Company consummates a public offering, then upon the later to occur of (i) five business days after the Company receives the net cash proceeds therefrom or (ii) May 15, 2023, the Duggan February Note and the Zanganeh Note shall be prepaid by an amount equal to the lesser of (a) 100% of the amount of the net proceeds of such offering and (b) the outstanding principal amount on such Notes.

On January 19, 2023, the Company provided notice to extend the term of the Duggan February Note and Duggan September Note to a maturity date of September 6, 2024. Furthermore, on January 19, 2023, the Company and Mr. Duggan rectified the Duggan February Note and Duggan September Note in order to correctly reflect the parties' intent that the Company may only prepay (i) the Duggan February Note following the completion of a public rights offering to be conducted by Summit in the approximate amount of \$500,000, or a similar capital raise, in an amount equal to the lesser of (x) the net proceeds of the Rights Offering or such capital raise or (y) the full amount outstanding of the Duggan February Note, and (ii) Duggan September Note following the completion of a capital raising transaction subsequent to the 2023 Rights Offering in an amount equal to the lesser of (A) the net proceeds of such capital raise or (B) the full amount outstanding of the Duggan September Note. Following the issuance of the two new Promissory Notes (the "Duggan Promissory Notes"), the Duggan February Note and Duggan September Note were marked as "cancelled" on their face and replaced in their entirety by the Duggan Promissory Notes (together with the Zanganeh Note, the "Notes").

On February 15, 2023, the \$20,000 Zanganeh Note matured and the Company repaid the outstanding principal balance. In connection with the closing of the 2023 Rights Offering, the \$400,000 Duggan Promissory Note matured and became due, and the Company satisfied all principal and accrued interest thereunder using a combination of a portion of the cash proceeds from the 2023 Rights Offering and the extinguishment of a portion of the amount due equal to the subscription price for shares subscribed by Mr. Duggan in the 2023 Rights Offering.

The Notes accrued interest at an initial rate of 7.5%. All interest on the Notes was paid on the date of signing for the period through February 15, 2023. Such prepaid interest was paid in a number of shares of the Company's common stock, par value \$0.01 ("Common Stock") equal to the dollar amount of such prepaid interest, divided by \$0.7913 (the consolidated closing bid price immediately preceding the time the Company entered into the Note Purchase Agreement, plus \$0.01), which was 9,720,291 shares. For all applicable periods following February 15, 2023, interest shall accrue on the outstanding principal balance of the Notes at the US prime interest rate, as reported in the *Wall Street Journal*, plus 50 basis points, as adjusted monthly, for three months immediately following February 15, 2023, and thereafter at the US prime rate plus 300 basis points, as adjusted monthly. Such accrued interest shall be paid in cash, quarterly in arrears, on each of March 31, June 30, September 30 and December 31.

Debt issuance costs associated with the Notes were \$44 and were capitalized as part of the carrying value of the promissory notes payable to related parties.

On February 17, 2024, the Duggan February Note was amended and restated to extend the maturity date from September 6, 2024 to April 1, 2025. For all applicable periods commencing February 17, 2024, interest shall accrue on the outstanding principal balance at the greater of 12% or the US prime interest rate, as reported in the *Wall Street Journal* plus 350 basis points, as adjusted monthly, and compounded quarterly. Interest shall be paid upon maturity of the loan.

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The debt discount is amortized to interest expense using an effective interest rate method. The effective interest rate of the Duggan February Note and Zanganeh Note was 8.9% and the effective interest rate of the Duggan September Note is 11.0%.

During the three and nine months ended September 30, 2024, the Company incurred interest expense of \$2,455 and \$8,677, respectively. During the three and nine months ended September 30, 2023, the Company incurred interest expense of \$2,722 and \$13,564, respectively. Interest expense incurred during the nine months ended September 30, 2023 included amortized imputed interest of \$761. As of September 30, 2024, accrued interest was \$7,294 and was recorded in accrued liabilities. As of December 31, 2023, accrued interest was \$120 and was recorded in accrued liabilities.

On September 16, 2024, the Company used some of the proceeds raised from the September 2024 Private Placement (see Note 15 for further details) to repay \$75,500 in principal on the Duggan September Note, thus reducing the outstanding current note payable balance to \$24,500 as of September 30, 2024.

On October 1, 2024, the Company repaid the Duggan September Note in full, resulting in principal payments of \$24,500 and accrued cash interest of \$7,305.

15. Stockholders' Equity

Preferred Stock

As of September 30, 2024 and December 31, 2023, the Company had 20,000,000 shares of preferred stock, par value \$0.01 authorized and no shares issued and outstanding.

Common Stock

As of September 30, 2024 and December 31, 2023, the Company had authorized 1,000,000,000 shares of common stock, par value \$0.01 (the "Common Stock"). As of September 30, 2024 and December 31, 2023, the Company had 737,094,965 shares and 701,660,053 shares of Common Stock issued and outstanding, respectively.

June 2024 PIPE

On June 3, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with 667, L.P. and Baker Brothers Life Sciences, L.P., affiliates of Baker Bros. Advisors, L.P. (the "Investors"), for the sale by the Company in a private placement (the "June 2024 Private Placement") of 22,222,222 shares (the "Shares") of Common Stock, at purchase price of \$9.00 per share, for an aggregate purchase price of approximately \$200,000.

The closing of the June 2024 Private Placement was subject to the satisfaction of certain customary closing conditions, which were achieved on June 6, 2024. The Purchase Agreement contained customary representations, warranties and covenants by the Company, customary indemnification obligations of the Company, including for liabilities under the Securities Act of 1933, other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Purchase Agreement were made only for purposes of the Purchase Agreement and as of specific dates, were solely for the benefit of the parties to such agreements and were subject to limitations agreed upon by the contracting parties.

On June 3, 2024, in connection with the Purchase Agreement, the Company entered into a Registration Rights Agreement with the Investors (the "Registration Rights Agreement"). The Registration Rights Agreement provides, among other things, that the Company will as soon as reasonably practicable, file with the SEC a registration statement registering the resale of the Shares. The Company agreed to use its reasonable best efforts to have such registration statement declared effective as soon as practicable after the filing thereof. The Company filed the registration statement on August 6, 2024, which was automatically effective upon filing.

September 2024 PIPE (Private Investment in Public Equity)

On September 11, 2024, the Company entered into securities purchase agreements (the "September 2024 Purchase Agreements") with multiple leading biotech institutional investors and individual accredited investors (the "September 2024 Investors"), for the sale by the Company in a private placement (the "September 2024 Private Placement") of an aggregate of 10,352,418 shares (the "September 2024 Shares") of the Company's common stock, par value \$0.01 per share of Common Stock, at purchase price of \$22.70 per Share, which was the closing price of the Common Stock on September 11, 2024, for aggregate gross proceeds to the Company of approximately \$235,000, with offering costs of \$140.

All of the Company's Section 16 officers participated in the capital raise. A total of \$79,000 was raised by the Company's Chief Executive Officer ("CEO"), Executive Chairman and majority stockholder, its CEO and the President and member of

the Company's Board of Directors (the "Board"), the Chief Operating Officer ("COO") and Chief Financial Officer ("CFO"), the Chief Accounting Officer ("CAO"), and a member of the Board of Directors, who invested via a controlled entity. The remaining \$156,000 was raised with multiple leading biotech institutional investors. Refer to Note 17 Related Party Transactions for further details regarding related parties' participation.

The closing of the September 2024 Private Placement was September 13, 2024. The Purchase Agreements contain customary representations, warranties and covenants by the Company, customary indemnification obligations of the Company, including for liabilities under the Securities Act, as amended (the "Securities Act"), other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Purchase Agreements were made only for purposes of the Purchase Agreements and as of specific dates, were solely for the benefit of the parties to such agreements and were subject to limitations agreed upon by the contracting parties.

On September 11, 2024, in connection with the September 2024 Purchase Agreements, the Company entered into Registration Rights Agreements with the Investors (the "September 2024 Registration Rights Agreements"). The September 2024 Registration Rights Agreements provide, among other things, that the Company will as soon as reasonably practicable file with the SEC a registration statement registering the resale of the Shares. The Company filed the registration statement on September 19, 2024, which was automatically effective upon filing.

At-the-Market Offering (ATM Offering)

On May 13, 2024, the Company entered into an at-the-market sales agreement (the "ATM Agreement") pursuant to which the Company may, subject to the terms and conditions set forth in the agreement offer and sell, from time to time, through or to the agents, acting as agents or principal, shares of the Company's common stock, par value \$0.01, having an aggregate offering price of up to \$90,000.

During the three months ended and from the date of the ATM Agreement through September 30, 2024, the Company sold 1,807,093 shares of common stock under the ATM Agreement at a weighted-average price of \$24.47 per share, for gross proceeds of \$44,223. The remaining availability under the ATM Agreement as of September 30, 2024 is approximately \$45,777.

The Company has received net proceeds of \$43,033, which is net of sales commissions and other offering fees of approximately \$1,190. The Company plans to use the net proceeds from this offering for working capital and general corporate purposes.

16. Stock-Based Compensation and Warrants

Stock-Based Compensation

The Company currently grants stock options to employees and directors under the 2020 Stock Incentive Plan (the "2020 Plan") and formerly, the Company granted stock options under the 2016 Long Term Incentive Plan (the "2016 Plan"). The 2020 Plan is administered by the Compensation Committee of the Board. The 2020 Plan is intended to attract and retain employees and directors and provide an incentive for these individuals to assist the Company to achieve long-range performance goals and to enable these individuals to participate in the long-term growth of the Company.

On May 3, 2024, the Board adopted the 2024 Inducement Pool (the "Inducement Pool"), which mirrors the terms of the 2020 Plan, with a total of 2,000,000 shares of common stock reserved for issuance under the Inducement Pool. The Inducement Pool provides for the grant of non-qualified stock options and was approved by the Compensation Committee of the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Inducement Pool is administered by the Compensation Committee of the Board. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, non-qualified stock options under the Inducement Pool may only be made to an employee who has not previously been an employee of the Company or member of the Board (or any parent or subsidiary of the Company), if he or she is granted such non-qualified stock options in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. As of September 30, 2024, there were 914,750 shares available for grant under the Inducement Pool.

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The following table summarizes the Company's time-based stock option activity for the nine months ended September 30, 2024:

	Number of Options	Weighted average exercise price
Outstanding at December 31, 2023	54,209,289	\$ 2.28
Granted	7,400,074	\$ 4.69
Forfeited	(1,552,537)	\$ 2.17
Exercised	(629,628)	\$ 2.29
Outstanding at September 30, 2024	<u>59,427,198</u>	<u>2.58</u>
Exercisable at September 30, 2024	<u>7,115,267</u>	<u>4.88</u>

The total intrinsic value of all outstanding time-based stock options and exercisable stock options at September 30, 2024 was \$1,148,062 and \$121,106, respectively. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The following table summarizes the Company's performance-based stock option activity for the nine months ended September 30, 2024:

	Number of Options	Weighted average exercise price
Outstanding at December 31, 2023	46,654,220	\$ 1.62
Granted	2,825,000	\$ 4.14
Forfeited	(1,089,000)	\$ 1.34
Outstanding at September 30, 2024	<u>48,390,220</u>	<u>1.77</u>
Exercisable at September 30, 2024	<u>9,151,844</u>	<u>1.63</u>

The total intrinsic value of all outstanding performance-based and exercisable stock options at September 30, 2024 was \$973,991 and \$185,483, respectively.

During the three months ended September 30, 2024, the Company achieved certain market conditions, which resulted in 9,151,844 shares vesting and recognition of \$8,409 of compensation expense for the quarter, inclusive of accelerated charges of \$7,050 related to the accelerated vesting of these awards. Thus, as of September 30, 2024, total unrecognized compensation expense related to performance-based stock options that were deemed probable of vesting was nil.

The number of unvested performance-based stock options that were deemed not-probable of vesting and the related unrecognized stock-based compensation expense is 39,238,376 and \$52,716, respectively.

The total stock-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive loss was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 5,819	\$ 149	\$ 11,747	\$ 1,962
General and administrative	13,552	556	28,219	3,393
Total stock-based compensation expense	<u>\$ 19,371</u>	<u>\$ 705</u>	<u>\$ 39,966</u>	<u>\$ 5,355</u>

The following summarizes share-based compensation expense associated with each of the Company's stock-based compensation arrangements:

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	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Time-based stock options	\$ 10,803	\$ 613	\$ 28,614	\$ 5,093
Performance-based stock options	8,409	51	11,031	144
Employee stock purchase plan	159	41	321	118
Total stock-based compensation expense	<u>\$ 19,371</u>	<u>\$ 705</u>	<u>\$ 39,966</u>	<u>\$ 5,355</u>

Warrants

The Company had outstanding and exercisable warrants of 4,945,669 and 5,015,642 with a weighted average exercise price of \$1.58 and \$1.57 as of September 30, 2024 and December 31, 2023, respectively. Warrants of 69,973 with a weighted average exercise price of \$1.44 were exercised during the nine months ended September 30, 2024.

17. Related Party Transactions

Lease Agreements

July 25, 2022 First Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc.

On July 25, 2022 the Company entered into a first amendment, dated July 19, 2022, to its existing sublease agreement with Maky Zanganeh and Associates, Inc. ("MZA"), consisting of 4,500 square feet of office space at 2882 Sand Hill Road, Menlo Park, California. The existing sublease term, which was set to expire on September 30, 2022, was extended for a period of thirty-nine months from October 1, 2022 through December 31, 2025. The rent payable under the terms of the sublease is equivalent to the proportionate share of the net payable by MZA to the third-party landlord, based on the square footage of office space sublet by the Company, and no mark-up has been applied. The agreement was further amended to include additional space, as noted below under "August 2, 2024 Third Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc." During the three and nine months ended September 30, 2024, payments of \$199 and \$588, respectively, were made pursuant to the first and third amendments to the Sublease Agreement. During the three and nine months ended September 30, 2023, payments of \$189 and \$567, respectively, were made pursuant to the first amendment to the Sublease Agreement.

July 29, 2022 Second Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc.

On July 29, 2022, the Company entered into a second amendment, dated August 1, 2022, to its existing sublease agreement with MZA, described above. The second amendment was effective as of August 1, 2022 and expires on December 31, 2025. The second amendment includes an additional 1,277 square feet (the "Expansion Premises") of office space at 2882 Sand Hill Road, Menlo Park, California. The rent payable under the terms of the sublease is equivalent to the proportionate share of the net payable by MZA to the third-party landlord, based on the square footage of office space sublet by the Company, and no mark-up has been applied. During the three and nine months ended September 30, 2024, payments of \$57 and \$167, respectively, were made pursuant to the second amendment to the Sublease Agreement. During the three and nine months ended September 30, 2023, payments of \$55 and \$163, respectively, were made pursuant to the second amendment to the Sublease Agreement.

April 1, 2024 Miami Sublease Agreements

On April 1, 2024, the Company entered into two sublease agreements of its Miami headquarters location, one with Genius 24C Inc. ("Genius"), an affiliate of the Company's CEO, Robert W. Duggan (the "Genius Sublease Agreement") and one with Duggan Investments Research LLC ("Investments Research"), also an affiliate of the Company's CEO, Robert W. Duggan (the "Investments Research Sublease Agreement"). Pursuant to the Genius Sublease Agreement, Genius will sublease from the Company 848 square feet of office space in the Miami HQ for a sixty-two month term for total rental payments of approximately \$446. Pursuant to the Investments Research Sublease Agreement, Investments Research will sublease from the Company 848 square feet of office space in the Miami HQ for a sixty-two month term for total rental payments of approximately \$446. For the three and nine months ended September 30, 2024, the Company has recognized \$57 and \$105.

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respectively, of sublease income recorded net of operating lease expenses, and recorded \$90 in other receivables on the condensed consolidated balance sheet as of September 30, 2024.

August 2, 2024 Third Amendment to Sublease Agreement with Maky Zanganeh and Associates, Inc.

On August 2, 2024, the Company entered into a third amendment to its existing sublease agreement with MZA. The third amendment has an effective date of August 1, 2024, which includes an additional space of 145 square feet of office space at 2882 Sand Hill Road, Menlo Park, California. The Company continues to be obligated to pay its proportionate share of the net payable by MZA to the third-party landlord, which is revised to 93.6% as of the effective date, based on the square footage of office space sublet by the landlord.

Promissory Note Payable to Related Parties

Refer to Note 14 for a discussion of the promissory note payables to related parties issued December 6, 2022 and fully repaid on October 1, 2024.

Akeso Collaboration and License Agreement

Upon the closing of the License Agreement, the Board of the Company appointed Dr. Yu (Michelle) Xia to serve as a member of the Board pursuant to the terms of the License Agreement. Dr. Xia is the founder of Akeso, Inc. ("Akeso"), and has been the chairwoman, president and CEO of Akeso since its inception in 2012. For details on the License Agreement and Second Amendment entered into on June 3, 2024, see Note 7. Furthermore, in connection with the License Agreement, the Company also entered into a Supply Agreement with Akeso, pursuant to which Summit agreed to purchase a certain portion of drug substance for clinical and commercial supply (the "Supply Agreement").

2023 Rights Offering

On December 6, 2022, the Company announced a rights offering for its existing shareholders to participate in the purchase of additional shares of its Common Stock for \$1.05 per share. The 2023 Rights Offering commenced on February 7, 2023 and the associated subscription rights expired on March 1, 2023. Aggregate gross proceeds from the 2023 Rights Offering were \$500,000 from the sale of 476,190,471 shares of Common Stock and issuance costs were \$619. Mr. Duggan and Dr. Zanganeh fully subscribed to their respective basic subscription rights at a price of \$1.05 per share. To satisfy the \$395,314 subscription price for the shares subscribed by Mr. Duggan in the 2023 Rights Offering, Mr. Duggan agreed with the Company to extinguish a portion of the amount due and payable to him by the Company at the closing of the 2023 Rights Offering pursuant to the \$400,000 Duggan Promissory Note in an amount equal to the subscription price.

Private Placements

October 2023

On October 16, 2023, the Company announced the appointment of Mr. Manmeet Soni as its COO, effective immediately. Mr. Soni has been a part of the Board since 2019. He remains a member of the Board. In conjunction with his appointment, Mr. Soni entered into a share purchase agreement with the Company to invest \$5,000 in shares of Common Stock via a private placement. The transaction was effective October 13, 2023 with a closing price of \$1.68 per share, resulting in the purchase of 2,976,190 shares of Common Stock.

September 2024

On September 11, 2024, the Company's Section 16 officers participated in the "September 2024 Purchase Agreements" along with multiple leading biotech institutional investors, for the sale by the Company in the September 2024 Private Placement for an aggregate of 10,352,418 shares of the Company's common stock, par value \$0.01 per share of Common Stock, at purchase price of \$22.70 per Share, which was the closing price of the Common Stock on September 11, 2024, for aggregate gross proceeds to the Company of approximately \$235,000.

The Company's CEO and Executive Chairman, Mr. Robert W. Duggan, purchased 3,325,991 shares for an aggregate purchase price of \$75,500, CEO, President and member of its Board, Dr. Mahkam Zanganeh, purchased 44,052 shares for an aggregate purchase price of \$1,000, COO and CFO, Manmeet Soni, purchased 44,052 shares for an aggregate purchase price of \$1,000, and member of the Board, Jeff Huber, through his controlled entity, Caspian Capital LLC, purchased 44,052

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shares for an aggregate purchase price of \$1,000, with their collective participation in the September 2024 Private Placement totaling 3,458,147 shares of Common Stock for an aggregate purchase price of \$78,500.

The Company used some of the proceeds raised from the September 2024 Private Placement to repay \$75,500 in principal on the Duggan September Note. See Note 14 for additional details regarding the promissory note payable to a related party.

18. Commitments and Contingencies

Lease Commitments

There were no material changes to the Company's lease commitments that were disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC, other than the new lease for the Miami, FL headquarter location as described in Note 12.

Debt Commitments

Refer to Note 14 for discussion on the promissory note payable to a related party.

Other Commitments

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. Most contracts provide for termination upon notice, and therefore are cancellable contracts. The majority of these commitments are due within one year. There have been no material changes to the Company's other contractual commitments that were disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Indemnifications

The Company's certificate of incorporation provides that it will indemnify the directors and officers to the fullest extent permitted by Delaware law. In addition, the Company has entered into indemnification agreements with all of the directors and executive officers. These indemnification agreements may require the Company, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of the Company's directors or executive officers. The Company believes the fair value for these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of September 30, 2024 and December 31, 2023.

Legal Proceedings

The Company is not currently subject to any material legal proceedings.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included herein and our audited consolidated financial statements and related notes for the year ended December 31, 2023 included in our Annual Report on Form 10-K, filed on February 20, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this filing, including information with respect to our plans and strategy for our business, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we “believe,” “expect,” “anticipate,” “plan,” “target,” “intend” and similar expressions should be considered forward-looking statements. As a result of many factors, including those factors set forth in the risks identified the “Risk Factors” section of our other filings with the Securities and Exchange Commission, or the SEC, our actual results could differ materially from the results, performance or achievements expressed in or implied by these forward-looking statements.

Company Overview

Summit Therapeutics Inc. (“we”, “Summit” or the “Company”) is a biopharmaceutical company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs. The Company’s pipeline of product candidates is designed with the goal to become the patient-friendly, new-era standard-of-care medicines, in the therapeutic area of oncology.

The Company’s current lead development candidate is ivonescimab, a novel, potential first-in-class bispecific antibody intending to combine the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects of an anti-VEGF compound into a single molecule. On December 5, 2022, the Company entered into a Collaboration and License Agreement (the “License Agreement”) with Akeso, Inc. and its affiliates (“Akeso”) pursuant to which the Company has in-licensed ivonescimab. Through the License Agreement, the Company obtained the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan. The License Agreement and transaction closed in January 2023 following customary waiting periods. On June 3, 2024, the Company entered into an amendment to the License Agreement with Akeso to expand its territories covered under the License Agreement to also include the Latin America, Middle East and Africa regions (collectively, and as expanded, the “Licensed Territory”). The Company’s operations are focused on the development of ivonescimab and other future activities, as the Company determines.

The Company has begun its development for ivonescimab in non-small cell lung cancer (“NSCLC”), specifically launching Phase III clinical trials in the following proposed indications:

- a) ivonescimab combined with chemotherapy in patients with epidermal growth factor receptor (“EGFR”)-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with a third-generation EGFR tyrosine kinase inhibitor (“TKI”) (“HARMONi”); and
- b) ivonescimab combined with chemotherapy in first-line metastatic squamous NSCLC patients (“HARMONi-3”)

In addition, the Company announced its intention to initiate a Phase III clinical study in the following proposed indication in early 2025:

- c) ivonescimab monotherapy in first-line metastatic NSCLC patients with high PD-L1 expression (“HARMONi-7”).
 - The sample size for this study is currently planned to have an estimated 780 patients with two primary endpoints, progression-free survival (PFS) and overall survival (OS)

On October 3, 2024, the Company announced that it had completed enrollment in its HARMONi clinical trial and expects to disclose topline results from HARMONi in mid-2025, depending upon maturation of the data per the protocol.

The Company recently announced that it has the intention to amend the protocol for its HARMONi-3 study to include both squamous and non-squamous patients without actionable genomic alterations, adjust the primary endpoint for HARMONi-3 to include PFS in addition to OS, and adjust the sample size to include an estimated 1,080 patients.

The entry into the License Agreement with Akeso represented a significant change in the Company's strategy and its future operations will be focused on the development of ivonescimab and other future activities as the Company determines. Our portfolio also includes ridinilazole, a product candidate for treating patients suffering from *Clostridioides difficile* infection, also known as *C. difficile* infection, or CDI, and SMT-738, the first of a novel class of precision antibiotics for combating multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae ("CRE") infections. All prior development activities related to ridinilazole and SMT-738 have been terminated; we may explore partnership opportunities for both assets.

Akeso Collaboration and License Agreement

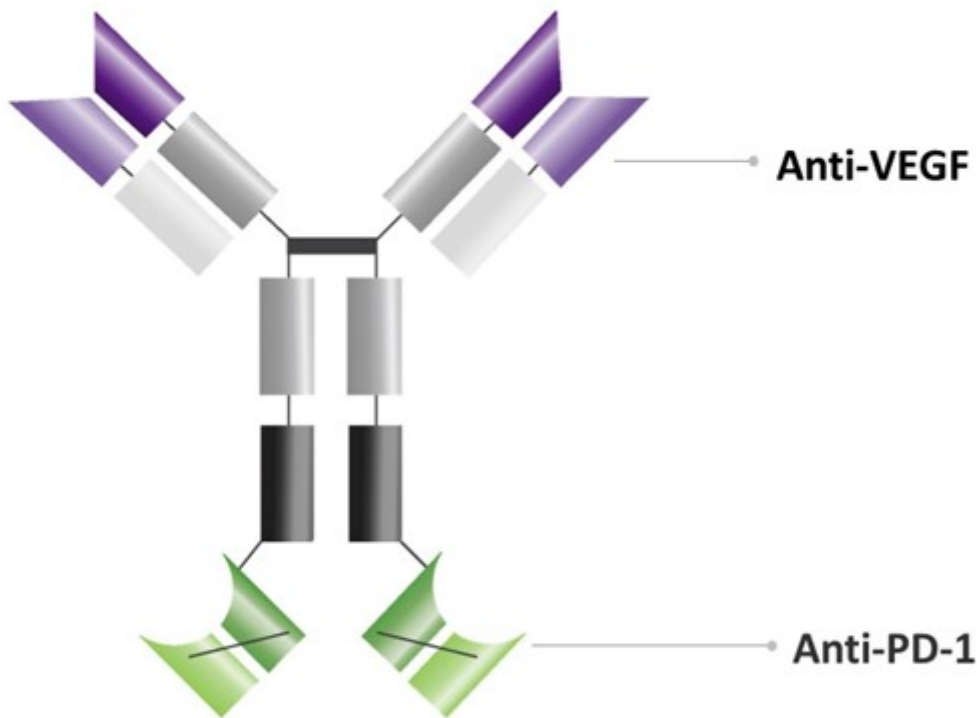
Pursuant to the License Agreement with Akeso, the Company received the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan. Akeso will retain development and commercialization rights for the rest of the world excluding such licensed territories. In exchange for these rights, Summit made an upfront payment during the first quarter of 2023 comprised of \$474.9 million cash and the issuance of 10 million shares of the Company's common stock in lieu of \$25.1 million cash pursuant to a share transfer agreement. Furthermore, on June 3, 2024, the Company entered into an amendment to the License Agreement with Akeso to expand its territories covered under the License Agreement to also include the Latin America, Middle East and Africa regions (collectively, and as expanded, the "Licensed Territory"), for which Summit paid an upfront payment of \$15.0 million cash in the third quarter of 2024. In addition, the Company will potentially owe Akeso (a) milestone payments tied to achievement of regulatory approval of ivonescimab with various regulatory authorities in the Licensed Territory (b) milestone payments tied to achievement of annual revenue from ivonescimab in the Licensed Territory and (c) royalty payments equal to low-double-digit percentage of annual revenues from ivonescimab in the Licensed Territory.

Pursuant to the terms of the License Agreement, Summit will have final decision-making authority with respect to clinical development strategy and execution in the Licensed Territory. For co-joined studies in which both Summit and Akeso participate, mutual agreement is required for material decisions; Summit retains the exclusive decision making with respect to participating in, and continuing its participation in, co-joined studies. In connection with the License Agreement, the Company has also agreed to enter into a Supply Agreement with Akeso (the "Supply Agreement"). Pursuant to the Supply Agreement, Summit agreed to purchase a certain portion of drug substance for clinical and commercial supply. Pursuant to the terms of the License Agreement, Summit will have final decision-making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters in the Licensed Territory.

Summit has not assumed any liabilities (including contingent liabilities), nor acquired any physical assets or trade names, or hired or acquired any employees from Akeso in connection with the License Agreement.

Ivonescimab

Ivonescimab is a novel potential first-in-class PD-1 / VEGF bispecific antibody, believed to be the most advanced in clinical development in the Licensed Territory; there are no known PD-1 / VEGF bispecific antibodies approved in our Licensed Territory. Engineered with Akeso's unique Tetrabody technology, ivonescimab, as a single molecule, blocks programmed cell death protein 1 ("PD-1") from binding to PD-L1 and PD-L2, and blocks vascular endothelial growth factor ("VEGF") from binding to VEGF receptors. Ivonescimab is designed to potentially allow cooperative binding of the intended targets, such that the binding of PD-1 increases the binding affinity of VEGF and the binding of VEGF increases the affinity towards PD-1. In view of the co-expression of VEGF and PD-1 in the tumor micro-environment ("TME"), ivonescimab may block these two pathways more effectively and enhance the antitumor activity, as compared to combination therapy through what is believed to be a differentiated cooperative binding mechanism.



This could differentiate ivonescimab as there is potentially higher expression (presence) of both PD-1 and VEGF in tumor tissue and the TME as compared to normal tissue in the body. As shown in Akeso's *in-vitro* studies, ivonescimab's tetravalent structure (four binding sites) enables higher avidity (accumulated strength of multiple binding interactions) in the tumor microenvironment with over 18-fold increased binding affinity to PD-1 in the presence of VEGF *in vitro*, and over 4 times increased binding affinity to VEGF in the presence of PD-1 *in vitro*. This tetravalent structure, the intentional novel design of the molecule, and bringing these two targets into a single bispecific antibody with cooperative binding qualities have the potential to direct ivonescimab to the tumor tissue versus healthy tissue. The intent of this design, together with a half-life of six to seven days, is to improve upon previously established efficacy thresholds, in addition to side effects and safety profiles associated with these targets.

In addition to the Phase III clinical trials sponsored by the Company, ivonescimab is also being developed in China and Australia by Akeso in multiple solid tumors and has been dosed in more than 1,800 patients globally.

HARMONi-A

Based on data published by Akeso at the 2024 Annual Meeting of the American Society of Clinical Oncology (ASCO 2024) and in a recent publication in the *Journal of the American Medical Association (JAMA)* in the HARMONi-A study, in a single-region (China), randomized, double-blinded Phase III study in patients with NSCLC who have progressed following an EGFR-TKI, ivonescimab achieved its primary endpoint of PFS when combined with doublet chemotherapy (pemetrexed and carboplatin). Patients experienced a 54% reduction in disease progression or death as compared to placebo plus doublet-chemotherapy (HR: 0.46, 95% CI: 0.34 - 0.62; $p < 0.001$). In a pre-specified subgroup analysis of patients who received a previous third-generation TKI, a hazard ratio of 0.48 was observed. A median Overall Survival (mOS) in this study of 17.1 months was observed, reflecting a 20% reduction in death as compared to placebo plus chemotherapy in the study (HR: 0.80, 95% CI: 0.59 - 1.08). The Phase III study was considered to have demonstrated a tolerable safety profile and a low discontinuation rate for adverse events.

HARMONi-2

After announcing positive qualitative results for the HARMONi-2 trial, also referred to as AK112-303, a randomized, single-region (China) Phase III study sponsored by Akeso, on May 30, 2024, the Company announced, on September 8, 2024, quantitative data from the primary analysis of the Phase III HARMONi-2 trial featuring ivonescimab that was presented as

part of the Presidential Symposium at the International Association for the Study of Lung Cancer’s (IASLC) 2024 World Conference on Lung Cancer (WCLC 2024). The HARMONi-2 presentation evaluated monotherapy ivonescimab compared to monotherapy pembrolizumab in patients with locally advanced or metastatic NSCLC whose tumors have positive PD-L1 expression. HARMONi-2 is a single region, multi-center, double-blinded Phase III study conducted in China sponsored by Akeso, with data generated and analyzed by Akeso.

In the HARMONi-2 primary analysis, ivonescimab monotherapy demonstrated a statistically significant improvement in the trial’s primary endpoint, PFS by Independent Radiologic Review Committee (IRRC), when compared to monotherapy pembrolizumab, achieving a hazard ratio of 0.51 (95% CI: 0.38, 0.69; p<0.0001). A clinically meaningful benefit was demonstrated across clinical subgroups, including patients with tumors with high PD-L1 expression. Overall survival data was not yet mature at the time of the data cutoff and will be evaluated in the future.

Ivonescimab demonstrated an acceptable and manageable safety profile, which was consistent with previous studies. There were three patients (1.5%) who discontinued ivonescimab due to treatment-related adverse events (TRAEs) compared to six patients (3.0%) who discontinued pembrolizumab due to TRAEs. There was one patient in the ivonescimab arm and two patients in the pembrolizumab arm who died as a result of TRAEs in this Phase III study.

Additional Phase II Data Sets

In addition to the HARMONi-2 data announced, on September 8, 2024 at the WCLC 2024, Akeso also announced the results from AK112-205, a single-region (China), multi-center, open-label Phase II study, sponsored by Akeso, of patients with Stage II or III resectable NSCLC, with data generated and analyzed by Akeso. Further, the Company announced that data for ivonescimab was presented as a part of the 2024 European Society for Medical Oncology Annual Meeting (ESMO 2024) featuring updated ivonescimab data in advanced triple-negative breast cancer (TNBC), recurrent / metastatic head and neck squamous cell carcinoma (HNSCC), and metastatic microsatellite-stable (MSS) colorectal cancer (CRC). Each trial from which the data was generated was a Phase II study conducted in China sponsored by Akeso, with data generated and analyzed by Akeso.

Based on data published by Akeso at the 2024 European Lung Cancer Conference, in the AK112-201 (Cohort 1), a Phase II study conducted in China, for first-line advanced NSCLC patients with squamous histology, (n=63), ivonescimab, combined with carboplatin and paclitaxel, demonstrated a median PFS of 11.1 months. For first-line advanced non-squamous NSCLC patients (n=72), ivonescimab, combined with carboplatin and pemetrexed, demonstrated a median PFS of 13.3 months. Median overall survival was not reached for either subgroup of patients after a median follow-up period of 22.1 months. This Phase II study was considered to have demonstrated a tolerable safety profile and a low discontinuation rate for adverse events.

Product Pipeline

Summit Sponsored Ivonescimab Trials: Ivonescimab is currently being investigated in global Phase III clinical trials. Phase I and II trials were completed by our partner Akeso. This pipeline reflects clinical trials that have been or are planned to be initiated by Summit in its Licensed Territory.

Indication	Study	Treatment Population	Regimen
NSCLC	HARMONi ¹	2L+ EGFRm	+ Chemo vs. chemo
	HARMONi ³	1L	+ Chemo vs. pembrolizumab (PD-1) + chemo
	HARMONi ⁷	1L PD-L1 High	Monotherapy vs. pembrolizumab (PD-1)

HARMONi study is a Phase III, multi-regional, potentially registration-enabling clinical trial that we joined with Akeso, and for which we started initiating and activating sites in North America and Europe during 2023. The first patient in our Licensed Territory was enrolled in the second quarter of 2023. We completed enrollment in October 2024. The two primary endpoints for this study are PFS and OS, and the study compares ivonescimab plus platinum-based doublet chemotherapy versus placebo plus platinum-based doublet chemotherapy. We expect to disclose top-line results from HARMONi in mid-2025, depending upon maturation of the data per the protocol.

The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the proposed use of ivonescimab in combination with platinum-based chemotherapy for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR mutation, who have experienced disease progression following EGFR-TKI therapy.

HARMONi-3 study is a Phase III, multi-regional, potentially registration-enabling clinical trial for which we initiated activating sites in North America and China during the fourth quarter of 2023. The primary endpoint for this study is overall survival (OS), and the study compares ivonescimab plus platinum-based doublet chemotherapy versus pembrolizumab plus platinum-based doublet chemotherapy. The Company continues to enroll patients in its HARMONi-3 clinical trial. The Company recently announced that it has the intention to amend the protocol for the HARMONi-3 study to include both squamous and non-squamous patients without actionable genomic alterations, adjust the primary endpoint for HARMONi-3 to include progression-free survival (PFS) in addition to overall survival (OS), and adjust the sample size to include an estimated 1,080 patients.

Based on the results of HARMONi-2, the Company announced its intention to initiate HARMONi-7 in early 2025. HARMONi-7 is currently planned as a multi-regional Phase III clinical trial that will compare ivonescimab monotherapy to pembrolizumab monotherapy in patients with metastatic NSCLC whose tumors have high PD-L1 expression. The sample size for this study is currently planned to have an estimated 780 patients with two primary endpoints, PFS and OS.

Summit plans to conduct its current clinical trials, as well as design and conduct additional clinical trial activities for ivonescimab within its Licensed Territory, to support and submit relevant regulatory filings. We intend to explore further clinical development of ivonescimab in solid tumor settings outside of metastatic non-small cell lung cancer, our current area of focus in its Phase III clinical trials.

In the fourth quarter of 2023, we began collaborating with multiple institutions globally and opened our investigator-initiated study program across several disease areas. In July 2024, we entered into a collaboration agreement with The University of Texas M.D. Anderson Cancer Center (MD Anderson) with the intent to further accelerate the development of ivonescimab through pre-clinical and clinical studies. Under the terms of the agreement, we have committed to MD Anderson \$15.0 million in milestone payments as compensation for services to be provided for the studies, over the five-year term of the collaboration agreement. Actual costs incurred under this collaboration are expensed to research and development as MD Anderson renders the services under the agreement. As of September 30, 2024, we have not provided any funding to MD Anderson and no research and development costs have been incurred.

In addition, our partners at Akeso are sponsoring multiple, ongoing Phase II and III clinical trials in NSCLC and other cancers outside of our Licensed Territory. We plan to review the data generated from these clinical trials as a part of our consideration for advancing our clinical development pipeline for ivonescimab in our Licensed Territory.

Recent Developments

Private Placement

On September 11, 2024, we entered into the Purchase Agreements with multiple leading biotech institutional and individual accredited investors (collectively, the “Investors”), for the sale by us in a private placement (the “September 2024 Private Placement”) of an aggregate of 10,352,418 shares (the “Shares”) of our common stock, at purchase price of \$22.70 per Share, which was the closing price of the common stock on September 11, 2024, for aggregate gross proceeds to us of approximately \$235.0 million (the “September 2024 Private Placement”). The closing of the September 2024 Private Placement occurred on September 13, 2024. The proceeds of the September 2024 Private Placement are expected to be used to advance, in part, the clinical development of ivonescimab, including in solid tumor settings outside of metastatic non-small cell lung cancer by leveraging the data that was presented at ESMO 2024, in addition to working capital needs and general corporate purposes, including, without limitation, the repayment of principal during the third quarter of 2024 in the amount of approximately \$75.5 million of the \$100.0 million promissory note issued by the Company to Robert W. Duggan, due April 1, 2025. The promissory note, including accrued interest, was subsequently repaid in full on October 1, 2024.

Our Chief Executive Officer, Executive Chairman and majority stockholder, Robert W. Duggan, Chief Executive Officer, President and member of the Board of Directors (the “Board”), Dr. Mahkam Zanganeh, Chief Operating Officer, Chief Financial Officer and member of the Board, Manmeet Soni, Chief Accounting Officer, Bhaskar Anand, and member of the Board, Jeff Huber, through his controlled entity Caspian Capital LLC, each participated as Investors in the Private Placement, purchasing an aggregate of 3,480,173 shares of common stock.

On September 11, 2024, in connection with the Purchase Agreements, we entered into Registration Rights Agreements with the Investors (the "Registration Rights Agreements"). The Registration Rights Agreements provide, among other things, that we will as soon as reasonably practicable file with the Securities and Exchange Commission (the "SEC") a registration statement registering the resale of the Shares. The Company filed the registration statement on September 19, 2024, which was automatically effective upon filing.

At-the-Market Offering

On May 13, 2024, the Company entered into an at-the-market sales agreement (the "ATM Agreement") pursuant to which the Company may, subject to the terms and conditions set forth in the agreement offer and sell, from time to time, through or to the agents, acting as agents or principal, shares of the Company's common stock, par value \$0.01, having an aggregate offering price of up to \$90.0 million.

During the three months ended and from the date of the ATM Agreement through September 30, 2024, the Company sold 1,807,093 shares of common stock under the ATM Agreement at a weighted-average price of \$24.47 per share, for gross proceeds of \$44.2 million. The remaining availability under the ATM Agreement as of September 30, 2024 is approximately \$45.8 million.

The Company has received net proceeds of \$43.0 million, which is net of sales commissions and other fees of approximately \$1.2 million. The Company plans to use the net proceeds from this offering for working capital and general corporate purposes.

Results of Operations

Amounts reported in millions within this Quarterly Report are computed based on the amounts in thousands, and therefore, the sum of components may not equal the total amount reported in millions due to rounding.

The following table sets forth our results of operations for the three and nine month periods ended September 30, 2024 and 2023:

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 37.7	\$ 15.3	\$ 99.4	\$ 34.7
Acquired in-process research and development	—	—	15.0	520.9
General and administrative	20.4	5.4	46.1	18.7
Total operating expenses	58.1	20.7	160.5	574.3
Other operating (expense) income, net	(0.3)	0.3	0.1	0.8
Operating loss	(58.4)	(20.4)	(160.4)	(573.5)
Other income (expense), net	2.1	(0.8)	0.3	(4.9)
Net loss	\$ (56.3)	\$ (21.2)	\$ (160.1)	\$ (578.4)

Operating Expenses

Research and Development and Acquired In-Process Research and Development Expenses

The table below summarizes our research and development expenses by category for the three and nine month periods ended September 30, 2024 and 2023, respectively.

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Oncology	\$ 23.0	\$ 10.5	\$ 64.8	\$ 19.3
Acquired in-process research and development	—	—	15.0	520.9
Anti-infectives	0.2	(0.1)	0.2	(1.3)
Compensation related costs, excluding stock-based compensation	8.7	4.8	22.6	14.7
Stock-based compensation	5.8	0.1	11.8	2.0
Total	\$ 37.7	\$ 15.3	\$ 114.4	\$ 555.6

Research and development expenses (excluding acquired in progress research and development noted below) increased by \$22.4 million and \$64.7 million during the three and nine month periods ended September 30, 2024, respectively, compared to the same periods in the prior year. This increase was primarily due to our continued investment in oncology expenses for ivonescimab, known as SMT112 in our Licensed Territory, resulting in an increase of \$12.5 million and \$45.5 million for the three and nine months periods ended September 30, 2024, respectively, and an increase in compensation and stock-based compensation related expenses of \$9.6 million and \$17.7 million in the three and nine months period ended September 30, 2024, respectively, to support the clinical development of ivonescimab as we continue to hire additional clinical resources in the oncology field, coupled with acceleration charges related to the achievement of certain market conditions on performance stock option awards, as described in Note 16 of our condensed consolidated financial statements included in this report. We expect oncology-related research and development costs to continue to increase as we progress with the development of ivonescimab.

In June 2024, we entered into a second amendment (the "Second Amendment") to the License Agreement with Akeso to expand our licensed territories to include Latin America, Middle East and Africa regions. Considered an extension of the

original License Agreement, we agreed to make an upfront payment to Akeso in the amount of \$15.0 million for these expanded territories which we paid in the third quarter of 2024. This was recorded in our condensed consolidated statement of operations and comprehensive loss as Acquired in process research and development expenses for the nine months ended September 30, 2024.

Our investment in ivonescimab totaled \$520.9 million for the nine months ended September 30, 2023 and primarily relates to our upfront milestone payments pursuant to the License Agreement with Akeso. The License Agreement closed in January 2023, and both Akeso and Summit entered into the Common Stock Issuance Agreement (“Issuance Agreement”). Pursuant to the License Agreement and Issuance Agreement, Akeso elected to receive 10 million shares of our common stock in lieu of \$25.1 million cash and was paid \$274.9 million in cash as the initial upfront payment. The remaining \$200.0 million upfront payment was paid on March 6, 2023. In-process research and development expense comprised of the \$474.9 million paid in cash, the fair value of the 10 million shares of common stock on the date of closing the transaction of \$45.9 million, and \$0.1 million of direct transactions costs incurred.

General and Administrative Expenses

The table below summarizes our general and administrative expenses by category for the three and nine month periods ended September 30, 2024 and 2023, respectively.

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Compensation related costs, excluding stock-based compensation	\$ 4.1	\$ 2.3	\$ 10.1	\$ 7.3
Stock-based compensation	13.6	0.6	28.2	3.4
Legal fees and professional services	(0.1)	1.3	3.0	4.9
Other general and administrative expenses	2.8	1.2	4.8	3.1
Total	\$ 20.4	\$ 5.4	\$ 46.1	\$ 18.7

General and administrative expenses increased by \$15.0 million and \$27.4 million for the three and nine months ended September 30, 2024, respectively, compared to the same period in the prior year, primarily due to an increase of \$13.0 million and \$24.8 million, respectively in stock-based compensation primarily due to acceleration charges related to the achievement of certain market conditions on performance stock option awards, as described in Note 16 of our condensed consolidated financial statements included in this report. Additionally, compensation-related costs, excluding stock-based compensation increased by \$1.8 million and \$2.8 million, for the three and nine months ended September 30, 2024, respectively, as the Company is focused on building its executive management team to continue supporting the growth of the Company. We expect our general and administrative costs to increase as we continue to support our development efforts in ivonescimab.

Other Operating (Expense) Income, net

The table below summarizes our other operating (expense) income, net for the three and nine month periods ended September 30, 2024 and 2023, respectively.

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development tax credits	\$ (0.3)	\$ 0.3	\$ 0.1	\$ 0.8
	<u>\$ (0.3)</u>	<u>\$ 0.3</u>	<u>\$ 0.1</u>	<u>\$ 0.8</u>

U.K. research and development tax credits decreased by \$0.6 million and \$0.7 million for the three and nine months ended September 30, 2024, compared to the same period in the prior year as management updated its estimates for qualifying expenditures relating to ivonescimab, which resulted in a decrease in tax credits claimed.

Other Income (Expense), net

The table below summarizes our other income (expense), net by category for the three and nine month periods ended September 30, 2024 and 2023, respectively.

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Foreign currency gains/(losses)	\$ 0.2	\$ (0.5)	\$ 0.2	\$ 0.3
Interest expense on promissory notes payable to related parties	(2.5)	(2.7)	(8.6)	(13.6)
Investment income	4.3	2.5	8.7	8.0
Reclassification of cumulative currency translation gain	—	—	—	0.4
Other expense, net	—	(0.1)	—	(0.1)
	<u>\$ 2.1</u>	<u>\$ (0.8)</u>	<u>\$ 0.3</u>	<u>\$ (4.9)</u>

For the three and nine months ended September 30, 2024, other expense, net primarily consisted of loan interest expense incurred related to the \$100 million promissory note as described in Note 14 to our condensed consolidated financial statements included in this report, for which \$24.5 million was outstanding as of September 30, 2024. These amounts for both periods presented are partially offset by investment income related to our money market funds and short-term investments in U.S. treasury securities. Investment income increased \$1.9 million and \$0.8 million for the three and nine months ended September 30, 2024, respectively, compared to the same period in the prior year, due to an overall increase in our money market funds and short-term investments balances.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through issuances of our common stock, including our most recent private placement issued in September 2024 for gross proceeds of \$235.0 million and the raise of \$44.2 million gross proceeds from our ATM Agreement, issuance of debt, receipt of payments to us under license, collaboration, and commercialization arrangements, for example, our license and commercialization agreement with Eurofarma Laboratórios SA, or Eurofarma, development funding and other assistance from government entities, philanthropic, non-government and not-for-profit organizations for our product candidates. In particular, we have received funding from BARDA, CARB-X, Innovate UK, Wellcome Trust and a number of not-for-profit organizations.

We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed the development of any drugs. We expect to continue to incur significant expenses and increasing operating losses for at least the next few years. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, due to the nature and timing of our research and development activities. We expect that our research and development and general and administrative expenses will continue to be significant in connection with our ongoing research and development efforts. In addition, if we obtain marketing approval for any of our product candidates in the United States or other jurisdictions where we retain commercial rights, and if we choose to retain those rights, we would expect to incur significant sales, marketing, distribution and outsourced manufacturing expenses, as well as ongoing research and development expenses. In addition, our expenses will increase if and as we:

- invest in clinical development of ivonescimab in our Licensed Territory;
- conduct research and continue development of additional product candidates;
- maintain and augment our intellectual property portfolio and opportunistically acquire complimentary intellectual property;
- seek further regulatory advancement for ivonescimab;
- invest in our manufacturing capabilities for ivonescimab and any other products for which we may obtain regulatory approval;
- seek marketing approvals for any product candidates that successfully complete clinical development;

- ultimately establish a sales, marketing and distribution infrastructure in jurisdictions where we have retained commercialization rights and scale up external manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- perform our obligations under our collaboration agreements;
- pursue business development opportunities, including investing in other businesses, products and technologies;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges
- hire additional clinical, regulatory, scientific and administrative personnel;
- expand our physical presence;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- borrow capital to fund our resources and have to pay interest expenses on such borrowings.

During the three and nine months ended September 30, 2024, we incurred a net loss of \$56.3 million and \$160.1 million, respectively, and cash flows used in operating activities for the nine months ended September 30, 2024 was \$93.4 million. As of September 30, 2024, we had an accumulated deficit of \$1,153.4 million, cash and cash equivalents of \$93.8 million, and short-term investments in U.S. treasury securities of \$393.1 million. We expect to continue to generate operating losses for the foreseeable future.

We have evaluated whether our cash, cash equivalents and short-term investments provide sufficient cash to fund our operating cash needs for the next 12 months from the date of issuance of these quarterly financials. We believe that our cash, cash equivalents, and short-term investments as of September 30, 2024 will fund our operating cash needs for at least the next 12 months from the date of issuance of these quarterly financials.

From time to time, we may raise additional equity or debt capital through both registered offerings off of a shelf registration, including “at-the-market” offerings, and private offerings of securities. On February 20, 2024, we filed a shelf registration statement on Form S-3 with the SEC, which the SEC declared effective on February 27, 2024. Through our shelf registration statement we may, from time to time, sell up to an aggregate of \$450 million of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units. Of the \$450 million of liquidity available to us under this shelf registration statement, on May 13, 2024, we had established an at-the-market offering program with J.P. Morgan Securities LLC, as sales agent, in the amount of up to \$90 million, of which \$45.8 million remains available for sale as of September 30, 2024. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are required and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected. As of the date of this report, additional capital has not been secured.

In addition to the payments already made to Akeso under the License Agreement and Second Amendment, there are additional potential milestone payments of \$4.56 billion, as Akeso will be eligible to receive regulatory milestones of up to \$1.05 billion and commercial milestones of up to \$3.51 billion. In addition, Akeso will be eligible to receive low double-digit royalties on net sales. Until we can generate substantial revenue and achieve profitability, we will need to raise additional capital to fund ongoing operations and capital needs, including the payment of the milestone payments referenced above.

We have based the foregoing estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support or through new collaboration arrangements. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of clinical trials required for clinical development of ivonescimab;
- the number and development requirements of other future product candidates that we pursue;
- the costs, timing and outcome of regulatory review of ivonescimab and/or our other product candidates we develop;
- the costs and timing of commercialization activities, including product sales, marketing, distribution and manufacturing, for any of our product candidates that receive marketing approval;
- the extent to which we become liable for milestone payments under the License Agreement and Second Amendment for ivonescimab;
- subject to receipt of marketing approval, revenue received from commercial sales of any product candidates;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims;
- our ability to establish and maintain collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the extent to which we acquire or invest in other businesses, products and technologies;
- the rate of the expansion of or the extent to which we change our physical presence.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of some, or all, of the following: equity and debt offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations, and marketing, distribution or licensing arrangements.

We will need to seek additional funding in the future to fund operations. Additional capital, when needed, may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends or other distributions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, which could materially adversely affect our business prospects or our ability to continue operations.

Cash Flows

The following table summarizes the results of our cash flows for the nine months ended September 30, 2024 and 2023:

(in millions)	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (93.4)	\$ (57.3)
Net cash used in investing activities	\$ (288.8)	\$ (648.3)
Net cash provided by financing activities	\$ 404.8	\$ 80.3

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was \$93.4 million and was due to a net loss of \$160.1 million, which included non-cash charges of \$35.5 million, an adjustment of \$15.0 million cash payments to investing activities, related to acquired-in process research and development for the upfront payment to Akeso for the Second Amendment signed in June 2024 and paid in the third quarter of 2024, and a net change in working capital of \$16.2 million. The non-cash charges primarily consisted of \$40.0 million of stock-based compensation, offset by \$4.9 million relating to the amortization of the discount of short-term investments in U.S. Treasury securities. The net change in working capital was primarily due to an increase of \$9.9 million in accrued liabilities, which mostly represents the interest on the current promissory notes payable, an increase of \$2.5 million in accrued compensation relating to an increase in accrued bonuses, a decrease of \$2.1 million in current and other long-term assets, a decrease of \$0.7 million in research and development tax receivable to reflect a true-up in estimates, an increase of \$0.5 million in accounts payable, and a decrease of \$0.6 million in prepaid expenses.

Net cash used in operating activities for the nine months ended September 30, 2023 was \$57.3 million and resulted from a net loss of \$578.4 million, which included an adjustment of \$475.0 million cash payments to investing activities for the purchase of in-process research and development from Akeso under the terms of the License Agreement and the associated direct transaction costs, non-cash charges of \$55.1 million and a net decrease in working capital of \$9.1 million. The non-cash charges primarily comprised of \$45.9 million issuance of shares in lieu of cash for Akeso upfront payment, \$5.9 million of non-cash interest expense, \$5.4 million of non-cash charges related to stock-based compensation, partially offset by \$1.7 million for amortization of discount on short-term investments. The net decrease in working capital was primarily due to a

decrease of \$9.9 million in accrued liabilities and accrued compensation, an increase of \$3.6 million in prepaid expenses and an increase of \$3.4 million in other current and long-term assets, partially offset by a decrease of \$4.3 million in the research and development tax credit receivable and an increase of \$2.9 million in accounts payable.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2024 was \$288.8 million and was primarily due to \$256.9 million received from the maturity, redemption and sale of short-term investments in U.S. Treasury securities, offset by \$530.5 million related to the purchase of short-term investments and \$15.0 million cash payment to Akeso for the Second Amendment signed in June 2024.

Net cash used in investing activities for the nine months ended September 30, 2023 primarily comprised of \$475.0 million cash payments made to Akeso for the upfront payment pursuant to the License Agreement, \$321.0 million for the purchase of short-term investments in U.S. treasury securities, partially offset by \$147.6 million received from the maturity and redemption of short-term investments in U.S. treasury securities.

Financing Activities

Net cash provided by financing activities was \$404.8 million for the nine months ended September 30, 2024, and primarily consisted of net proceeds of \$435.0 million from various private placements, \$43.0 million net proceeds from our current ATM Agreement, proceeds received of \$2.2 million related to employee stock awards, partially offset by \$75.5 million early principal repayment on the \$100.0 million promissory notes payable with a related party.

Net cash provided by financing activities was \$80.3 million for the nine months ended September 30, 2023, and was due to net proceeds received of \$104.1 million (net of paid issuance costs) related to the issuance of common stock from the 2023 Rights Offering and net of the extinguishment of \$395.3 million of principal and accrued interest due and payable by us under the \$400 million Duggan Promissory Note in satisfaction of the subscription price for the shares subscribed by Mr. Duggan in the 2023 Rights Offering, proceeds received of \$0.9 million related to employee stock awards, offset by the repayment of \$24.7 million related to promissory notes from related parties.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, research and development costs, intangible assets, stock-based compensation and income taxes. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, and in Critical Accounting Policies and Significant Judgments and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on February 20, 2024 (our "Annual Report"). There have been no material changes to our critical accounting policies and estimates that were disclosed in our Annual Report.

Contractual Obligations and Commitments

Lease Commitments

We lease office space in Menlo Park, California, Miami, Florida, United States and in Oxfordshire, United Kingdom. In addition to our lease commitments as of December 31, 2023, which were disclosed in our Annual Report, we entered into a new lease agreement for our Miami, Florida headquarters in the first fiscal quarter of 2024. Total future lease payments as of September 30, 2024, which include base rent and sales tax are approximately \$4.3 million on an undiscounted basis. This lease commenced on February 1, 2024 and has a term of 64 months. As of September 30, 2024, we have \$0.3 million of restricted cash associated with an irrevocable letter of credit required by the landlord to enter into this lease.

Debt Commitments

Refer to Note 14 to our condensed consolidated financial statements included in this report for a discussion of the promissory note payable to a related party.

Other Commitments

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. Most contracts provide for termination upon notice, and therefore are cancellable contracts. The majority of these commitments are due within one year. There have been no material changes to the Company's other contractual commitments that were disclosed in our Annual Report.

We have certain commitments under our agreements with Akeso, Wellcome Trust, the University College London and certain employees, former employees and former directors of Discuva, pursuant to which we will be required to pay royalties or make milestone payments. The License Agreement with Akeso also contains certain manufacturing and purchase commitments. As of September 30, 2024, we are unable to estimate the amount, timing or likelihood of achieving the milestones, making future product sales or assessing estimated forecasts for manufacturing and supplied materials which these contingent payment obligations relate to.

Indemnifications

Our certificate of incorporation provides that it will indemnify the directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of the directors and executive officers. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers. We believe the fair value for these

indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations as of September 30, 2024 and December 31, 2023.

Off-Balance Sheet Arrangements

Other than the contractual obligations and commitments described above, we did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued Accounting Pronouncements

For a discussion of recently issued accounting pronouncements, refer to Note 3, *Summary of Significant Accounting Policies and Recently Issued or Adopted Accounting Pronouncements*, to our condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Pursuant to Item 305(e) of Regulation S-K (§ 229.305(e)), the Company is not required to provide the information required by this Item as it is a “smaller reporting company,” as defined by Rule 229.10(f)(1).

Item 4. Controls and Procedures.

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) under the supervision and the participation of the Company’s management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officers and our Chief Financial Officer. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of September 30, 2024, our Chief Executive Officers and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently party to any material legal proceedings.

Item 1A. Risk Factors.

An investment in our common stock or other securities involves a number of risks. In addition to other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider each of the risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (our "Annual Report") filed with the Securities and Exchange Commission on February 20, 2024, which Annual Report includes a detailed discussion of the Company's risk factors. If any of the risks described therein or other uncertainties currently unknown to us, or that we currently deem to be immaterial, develop into actual events, our business, financial condition, or results of operations could be negatively affected, the market price of our common stock or other securities could decline, and you may lose all or part of your investment.

There have been no material changes to the risk factors disclosed in Item 1A of our Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

There were no unregistered sales of equity securities sold during the period covered by this Quarterly Report on Form 10-Q that were not previously included in a Current Report on Form 8-K filed by the Company.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None

Item 6. Exhibits.**Exhibit Index**

Exhibit No.	Description
3.1	<u>Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-36866), filed with the Securities and Exchange Commission on September 18, 2020)</u>
3.3	<u>Amendment to Restated Certificate of Incorporation of Summit Therapeutics Inc., as filed with the Delaware Secretary of State on July 27, 2022 (incorporated by reference to Exhibit 3.1 of Form 8-K filed by the Company on July 29, 2022, File No. 001-36866)</u>
3.4	<u>Amendment No. 2 to Restated Certificate of Incorporation, dated January 19, 2023 (incorporated by reference to Exhibit 5.1 of Form 8-K filed by the Company on January 20, 2023, File No. 001-36866)</u>
10.1†	Securities Purchase Agreement, dated September 11, 2024, by and among Summit Therapeutics Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the Company on September 12, 2024, File No. 001-36866)
10.2†	Registration Rights Agreement, dated September 11, 2024, by and among Summit Therapeutics Inc. and the Investors named therein (incorporated by reference to Exhibit 10.2 of Form 8-K filed by the Company on September 12, 2024, File No. 001-36866)
31.1*	<u>Certification of Chairman and Chief Executive Officer, Robert W. Duggan, pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Executive Director, Chief Executive Officer, and President, Dr. Mahkam Zanganeh, pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002</u>
31.3*	<u>Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to §302 of the Sarbanes-Oxley Act of 2002</u>
32.1**	<u>Certification of Chief Executive Officers and Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002</u>
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
*	Filed herewith.
**	Furnished herewith.
†	Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Company agrees to furnish supplementally a copy of all omitted exhibits and schedules to the SEC upon its request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: October 30, 2024

SUMMIT THERAPEUTICS INC.

By: /s/ Manmeet Soni
Name: Manmeet Soni
Title: Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Robert W. Duggan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Summit Therapeutics Inc. (the "Registrant");
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
 4. The Registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
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5. The Registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: October 30, 2024

By: _____ /s/ Robert W. Duggan
Name: **Robert W. Duggan**
Title: **Chairman and Co-Chief Executive Officer
(Principal Executive Officer)**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Dr. Mahkam Zanganeh, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Summit Therapeutics Inc.(the "Registrant");
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
 4. The Registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
 5. The Registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
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- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: October 30, 2024

By: _____ /s/ Mahkam Zanganeh
Name: **Dr. Mahkam Zanganeh**
Title: **Executive Director, Co-Chief Executive Officer, and President (Principal Executive Officer)**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Manmeet Soni, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Summit Therapeutics Inc. (the "Registrant");
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
 4. The Registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
 5. The Registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
-

- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: October 30, 2024

By: _____ /s/ Manmeet Soni
Name: **Manmeet Soni**
Title: **Chief Operating Officer and Chief Financial Officer**
(Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICERS AND PRINCIPAL FINANCIAL OFFICER PURSUANT
TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Summit Therapeutics Inc. (the “Company”) for the quarter ended September 30, 2024, as filed with the U.S. Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 30, 2024

By:	/s/ Robert W. Duggan
Name:	Robert W. Duggan
Title:	Chairman and Co-Chief Executive Officer (Principal Executive Officer)

Date: October 30, 2024

By:	/s/ Mahkam Zanganeh
Name:	Dr. Mahkam Zanganeh
Title:	Executive Director, Co-Chief Executive Officer, and President (Principal Executive Officer)

Date: October 30, 2024

By:	/s/ Manmeet Soni
Name:	Manmeet Soni
Title:	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer)